MALLINCKRODT

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Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, Maryland 20857

Re: Comment on the February 8, 2000 Draft Guidance Entitled, "Reprocessing and Reuse of Single Use Devices: Review Prioritization Scheme" (the RPS Guidance); **Docket No. 00D-0053**

Dear Sir or Madam:

Mallinckrodt Inc. (Mallinckrodt) respectfully submits the following comments in response to the Food and Drug Administration's (FDA's) Draft Guidance entitled, "Reprocessing and Reuse of Single Use Devices: Review Prioritization Scheme" (the RPS Guidance).[1] Mallinckrodt is a global health care company whose product lines include single use medical devices. Mallinckrodt is also a member of the Association of Disposable Device Manufacturers (ADDM) and agrees with ADDM's comments on the Review Prioritization Scheme (RPS). On pages 2-3 of the RPS Guidance, FDA acknowledged that the list in Appendix 2 of frequently reprocessed single use devices and their risk categorizations may be incomplete, and the Agency solicited comments on the list. Accordingly, Mallinckrodt submits these comments relating to Mallinckrodt's products and their categorization by the RPS. As explained below, we believe that FDA's risk categorization for urethral catheters is incorrect and should be revised. We also request that risk categorizations for two additional frequently reprocessed single use devices – tracheostomy inner cannulas and tracheal tube stylets – be added to Appendix 2.

I. Urethral Catheters (21 C.F.R. § 876.5130)

Mallinckrodt manufactures a specialized urethral catheter, known as a Foley catheter. The Foley catheter is a narrow flexible balloon retention type catheter inserted through the urethra and used to pass fluids from the urinary tract. Some models of the

[1] 65 Fed. Reg. 7027 (Feb. 11, 2000).

Foley catheter are enhanced with a temperature probe for measuring core body temperature. Mallinckrodt disagrees with FDA's conclusion in the RPS that reprocessed disposable urethral catheters are moderate risk devices. Under the analysis below they are high risk devices.

A. Infection Risk

1. Is the single use Foley catheter a non-critical device?

   No. Mallinckrodt's Foley catheters are not non-critical devices. According to the Spaulding criteria as defined by the RPS, a non-critical device is one that "is intended to make topical contact and not penetrate intact skin."[2] The Foley catheter is introduced into the patient through the urethra and is, therefore, a semi-critical device intended to contact intact mucous membranes.

2. Does postmarket information suggest that using the reprocessed single use Foley catheter may present an increased risk of infection when compared to the use of a single use Foley catheter that has not been reprocessed?

   No. Mallinckrodt is not aware of any postmarket information regarding risk of infection for reprocessed Foley catheters.

3. Does the single use Foley catheter include features that could impede thorough cleaning and adequate sterilization/disinfection?

   Yes. The Foley catheter is comprised of medical grade silicone or latex tubing containing two long narrow lumens, one for transport of fluids from the bladder and the other for the passage of air to inflate and deflate the balloon component in the bladder. The role of the balloon is to ensure catheter retention within the bladder. The long narrow lumens cannot be adequately cleaned. Urinary catheters are prone to deposit build-up. Such deposits are very difficult to remove from the internal surface of the catheter. In addition, the insufflation lumen contains a spring-loaded valve on the proximal end. The valve mechanism creates many crevices and difficult-to-reach areas where contaminants may accumulate. Because these devices were not designed to be reprocessed, there is no way to properly access these areas for cleaning. Finally, the valve itself is made

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[2] RPS Guidance at 5.

from heat-sensitive plastic not designed for exposure to harsh cleaning chemicals or high temperature and humidity sterilization. The potential for infection caused by these features is of special concern in light of the high percentage of nosocomial infections that are urinary tract infections.[3]

4. Does a reusable device exist that has an equivalent design and the same intended use as the single use Foley catheter?

No. Mallinckrodt is not aware of a reusable device that has an equivalent design and the same intended use as the Foley catheter.

5. Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance document that may be used to determine if the single use Foley catheter has been adequately cleaned and disinfected/sterilized?

No. Mallinckrodt is not aware of any recognized performance standards or any CDRH guidance documents that may be used to determine if a Foley catheter has been adequately cleaned and sterilized. Mallinckrodt has not developed any performance tests that may be used to determine if any Foley catheters can be adequately cleaned and sterilized for multiple uses.

6. Is this a semi-critical device?

Yes. As discussed in the answer to question 1 above, these Foley catheters come in contact with intact mucous membranes and are therefore semi-critical devices.

Thus, application of FDA's risk infection flowchart demonstrates that Mallinckrodt's Foley catheters present a **moderate risk** of infection after reprocessing.

B. Inadequate Performance Risk

1. Does postmarket information suggest that using the reprocessed single use Foley catheters may present an increased risk of injury

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[3] Critical Care Nurse, 18(1):55-65 (Feb. 1998).

when compared to the use of a single use Foley catheter that has not been reprocessed?

No. Mallinckrodt is not aware of any postmarket information regarding risk of injury from reprocessed Foley catheters.

2. Could failure of the device cause death, serious injury or permanent impairment?

Yes. Failure of a Foley catheter could cause serious injury in several different ways. Of greatest concern is the potential that the balloon will fail to deflate within the bladder, thereby rendering standard removal impossible. In such a situation, surgical intervention with its concomitant risks would be required to remove the catheter. If the balloon fails to deflate and the catheter is clogged by deposits, the patient will require an emergency procedure to permit urine flow.

3. Does the single use Foley catheter contain any materials, coatings or components that may be damaged or altered by a single use or by reprocessing and/or resterilization in such a way that the performance of the device may be adversely affected?

Yes. The Foley catheter contains materials, coatings, and/or components that could be damaged or altered by reprocessing in such a way that the performance of the devices may be adversely affected. The spring-loaded valve discussed earlier is made of rigid plastic and is therefore bound to the silicone catheter by mechanical means, held in place by pressure and stress. Cleaning and sterilization may weaken this juncture allowing the valve to become dislodged. While all of Mallinckrodt's Foley catheters are made of silicone, we are aware that Foley catheters made of latex may undergo delamination and subsequent collapse of the inner lumen after reprocessing. Finally, some Foley catheters are equipped with a temperature sensor which may not be properly calibrated or functioning after reprocessing. An inaccurate temperature reading could result in administration of unnecessary intervention to the patient, or failure to administer intervention when indicated.

4. Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance document (which includes specifications, test protocols and acceptance criteria) that may be used to determine if the

performance of the single use Foley catheter has been altered due to reprocessing and use?

No. Mallinckrodt is not aware of any recognized performance standards or any CDRH guidance documents that may be used to determine if the performance of the single use Foley catheter has been altered due to reprocessing and use. While the American Society for Testing and Materials has developed a standard performance specification for the Foley catheter, the scope of that standard limits its applicability to short-term utilization of single use catheters and therefore fails to consider reuse. Mallinckrodt has not developed any performance tests that may be used to determine if the performance of the single use Foley catheter has been altered by reprocessing and subsequent use.

5. Can visual inspection determine if performance has been affected?

No, not in all cases. Visual inspection will not reveal whether the performance of the temperature probe has been affected by reprocessing.

Thus, application of FDA's risk of inadequate performance flowchart demonstrates that Foley catheters with temperature probes present a **high risk** of inadequate performance after reprocessing. Because a categorization of Foley catheters would necessarily include those with temperature sensors, Foley catheters should be categorized as **high risk** in Appendix 2 of the RPS Guidance.

II. Tracheostomy Inner Cannula (21 C.F.R. § 868.5800)

Mallinckrodt manufactures single use tracheostomy inner cannulas. Tracheostomy inner cannulas are devices which line the inner lumen of tracheostomy tubes to allow easy removal of lung secretion build-up without removal and reinsertion of the tracheostomy tube itself. Although these devices were not considered by FDA under the RPS Guidance, Mallinckrodt has determined that reprocessed tracheostomy inner cannulas are high risk devices.

A. Infection Risk

1. Are single use tracheostomy inner cannulas non-critical devices?

No. Mallinckrodt's tracheostomy inner cannulas are not non-critical devices. Tracheostomy inner cannulas are introduced into the patient through a tracheostomy tube inserted into a stoma in the patient's neck. Therefore, the device is a semi-critical device because it is intended to contact intact mucous membranes.

2. Does postmarket information suggest that using the reprocessed single use tracheostomy inner cannulas may present an increased risk of infection when compared to the use of single use tracheostomy inner cannulas that have not been reprocessed?

No. Mallinckrodt is not aware of any postmarket information regarding risk of infection for reprocessed tracheostomy inner cannulas.

3. Do the single use tracheostomy inner cannulas include features that could impede thorough cleaning and adequate sterilization/disinfection?

Yes. The connector which secures the device to the tracheostomy tube has interlocking parts that create crevices in which patient material and cleaning residuals may accumulate. As recognized by the RPS Guidance, interlocking parts are a feature that could impede cleaning.[4] In addition, single use tracheostomy inner cannulas are thin-walled devices not designed to withstand abrasive scrubbing and harsh cleaning chemicals, nor withstand high temperature and pressure sterilization.

4. Does a reusable device exist that has an equivalent design and the same intended use as the single use tracheostomy inner cannulas?

No. While reusable tracheostomy inner cannulas do exist, the designs of Mallinckrodt's single use cannulas are not equivalent to the designs of the reusable devices. For example, reusable tracheostomy inner cannulas are thicker walled, more robust devices than their disposable counterparts, and are designed to withstand repeated scrubbing. Moreover, the design of the connector on reusable devices is significantly different from that on disposable devices. Reusable device connectors include a threaded design which locks by twisting the inner cannulas into the tracheostomy tube. This design is able to properly lock the device hundreds of times.

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[4] RPS Guidance at 6.

Conversely, the disposable device connector is typically comprised of a clip design involving two plastic tabs on the inner cannulas. This design is susceptible to plastic fatigue after repeated use and can weaken and break.

5. Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance document that may be used to determine if the single use tracheostomy inner cannulas have been adequately cleaned and disinfected/sterilized?

No. Mallinckrodt is not aware of any recognized performance standards or any CDRH guidance documents that may be used to determine if the tracheostomy inner cannulas have been adequately cleaned and sterilized for use in another patient. Mallinckrodt does provide an information booklet to patients with instructions for cleaning reusable inner cannulas. These instructions, however, are based on reuse of the reusable device in the same patient. Mallinckrodt has not developed any performance tests that may be used to determine if any single use or reusable cannulas can be adequately cleaned and sterilized for multiple patients.

6. Is this a semi-critical device?

Yes. As discussed in Section II.A.1 above, these tracheostomy inner cannulas are semi-critical devices which come in contact with mucous membranes.

Thus, application of FDA's risk infection flowchart demonstrates that Mallinckrodt's tracheostomy inner cannulas present a **moderate risk** of infection after reprocessing. Review of the second flowchart demonstrates that the risk of inadequate performance of reprocessed tracheostomy inner cannulas is high.

B. Inadequate Performance Risk

1. Does postmarket information suggest that using the reprocessed single use tracheostomy inner cannulas may present an increased risk of injury when compared to the use of single use tracheostomy inner cannulas that have not been reprocessed?

No. Mallinckrodt is not aware of any postmarket information regarding risk of injury for reprocessed tracheostomy inner cannulas.

2. Could failure of the device cause death, serious injury or permanent impairment?

Yes. Failure of tracheostomy inner cannulas could cause serious injury. Failure of the airway connector due to weakened reprocessed plastic could occur at any time after the patient is initially ventilated. This type of failure would result in the patient becoming disconnected from the ventilator. If such failure occurs while the patient is unsupervised, the patient will be unable to breath, resulting in oxygen deprivation and death.

3. Do the single use tracheostomy inner cannulas contain any materials, coatings or components that may be damaged or altered by a single use or by reprocessing and/or resterilization in such a way that the performance of the device may be adversely affected?

Yes. The tracheostomy inner cannulas contains material, coatings, and/or components that could be damaged or altered by reprocessing in such a way that the performance of the devices may be adversely affected. As discussed in Section II.A.4 above, the locking mechanism between the tracheostomy tube and disposable inner cannulas is susceptible to fatigue from reprocessing. In addition, the thin plastic of the cannulas is not designed to withstand repeated scrubbing, harsh cleaning chemicals, or high temperature and pressure sterilization.

4. Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance document (which includes specifications, test protocols and acceptance criteria) that may be used to determine if the performance of the single use tracheostomy inner cannulas have been altered due to reprocessing and use?

No. Mallinckrodt is not aware of any recognized performance standards or any CDRH guidance documents that may be used to determine if the performance of the single use tracheostomy inner cannulas have been altered due to reprocessing and use. Mallinckrodt has not developed any performance tests that may be used to determine if the performance of the single use tracheostomy inner cannulas have been altered by reprocessing and subsequent use.

5. Can visual inspection determine if performance has been affected?

No. Visual inspection may not reveal whether the performance of the tracheostomy inner cannulas have been affected by reprocessing. Visual inspection would not reveal the weakened state of the airway connector that could fail while in use.

Thus, application of FDA's risk of inadequate performance flowchart demonstrates that Mallinckrodt's tracheostomy inner cannulas present a **high risk** of inadequate performance after reprocessing. Accordingly, the device itself should be categorized as **high risk** under FDA's RPS.

III. Tracheal Tube Stylet (21 C.F.R. § 868.5790)

Mallinckrodt manufactures single use tracheal tube stylets. The tracheal tube stylet is a closed lumen polyvinyl chloride tube with an aluminum rod core. The exterior surface of the device consists of a matte finish PVC with a thin layer of lubricant coating. The stylet is used to temporarily make rigid a flexible tracheal tube for insertion into the patient. Once the tracheal tube is inserted, the stylet is removed and the patient is ventilated. While tracheal tube stylets were not categorized by FDA under the RPS Guidance, Mallinckrodt has applied the RPS to these reprocessed devices and determined that they are high risk.

A. Infection Risk

1. Is the single use tracheal tube stylet a non-critical device?

No. Mallinckrodt's tracheal tube stylets are not non-critical devices. A tracheal tube stylet is introduced into the patient's esophagus through a tracheal tube and is therefore a semi-critical device because it is intended to contact intact mucous membranes.

2. Does postmarket information suggest that using the reprocessed single use tracheal tube stylet may present an increased risk of infection when compared to the use of a single use tracheal tube stylet that has not been reprocessed?

No. Mallinckrodt is not aware of any postmarket information regarding risk of infection for reprocessed tracheal tube stylet.

3. Does the single use tracheal tube stylet include features that could impede thorough cleaning and adequate sterilization/disinfection?

Yes. Disposable intubating stylets are not designed for reprocessing. High temperature sterilization could superheat the aluminum core of the device and thereby melt the PVC component.

4. Does a reusable device exist that has an equivalent design and the same intended use as the single use tracheal tube stylet?

No. While reusable intubating stylets do exist, their design is substantially different from that of disposable stylets. The reusable devices are typically made from a more durable material such as silicone or urethane, while the disposable device is made of PVC.

5. Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance document that may be used to determine if the single use tracheal tube stylet has been adequately cleaned and disinfected/sterilized?

No. Mallinckrodt is not aware of any recognized performance standards or any CDRH guidance documents that may be used to determine if the tracheal tube stylet has been adequately cleaned and sterilized. Mallinckrodt has not developed any performance tests that may be used to determine if any single use tracheal tube stylets can be adequately cleaned and sterilized for multiple uses.

6. Is this a semi-critical device?

Yes. As discussed in Section III.A.1 above, these tracheal tube stylets are semi-critical devices because they come in contact with mucous membranes.

Thus, application of FDA's risk infection flowchart demonstrates that Mallinckrodt's tracheal tube stylets present a **moderate risk** of infection after reprocessing.

B. Inadequate Performance Risk

1. Does postmarket information suggest that using the reprocessed single use tracheal tube stylet may present an

increased risk of injury when compared to the use of a single use tracheal tube stylet that has not been reprocessed?

Yes. In the attached paper from Anesthesia and Analgesia, Dr. Richard Fishman reports a serious injury in a foot surgery patient due to use of a reprocessed intubating stylet.[5] During a difficult intubation, a 10 cm piece of a reused disposable 14 FR stylet broke off in the esophagus. The broken stylet was not detected until several weeks later when the patient had acute stomach pains. The broken stylet fragment had perforated the duodenum.

While this response ends the flowchart with a high risk designation for these devices, below are responses to the remaining questions demonstrating that even without Dr. Fishman's experience, these devices are high risk.

2. Could failure of the device cause death, serious injury or permanent impairment?

Yes. Failure of a tracheal tube stylet could cause serious injury in several different ways. As noted by Dr. Fishman, reprocessing can lead to embrittlement and fracture of the stylet and subsequent serious injury caused by the sharp stylet traveling through the gastrointestinal tract. Serious injury or death can also be caused by difficulty in removing the stylet. Lack of lubrication and bends in the stylet caused by reprocessing may cause the stylet to catch on the tracheal tube causing its dislodgment. Due to airway swelling that typically occurs during intubation, reintroduction of the tracheal tube may be difficult. Moreover, time is of the essence in intubation since the patient is not breathing until the procedure is completed. Failure or delay in achieving an airway could lead to death or serious injury due to oxygen deprivation.

3. Does the single use tracheal tube stylet contain any materials, coatings or components that may be damaged or altered by a single use or by reprocessing and/or resterilization in such a way that the performance of the device may be adversely affected?

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5 Fishman, R. "Reuse of a Disposable Stylet with Life-Threatening Complications," Anesth and Analg, 72:266-267 (1991).

Yes. The tracheal tube stylet contains materials, coatings, and/or components that could be damaged or altered by reprocessing in such a way that the performance of the device may be adversely affected. As mentioned above, the lubricant coating on these devices may be removed during use and reprocessing. In addition, used stylets rarely return to their straight configuration, but rather remain somewhat bent. These bends and lack of lubricant can cause the device to become caught on the tracheal tube upon removal.

4. Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance document (which includes specifications, test protocols and acceptance criteria) that may be used to determine if the performance of the single use tracheal tube stylet has been altered due to reprocessing and use?

No. Mallinckrodt is not aware of any recognized performance standards or any CDRH guidance documents that may be used to determine if the performance of the single use tracheal tube stylet has been altered due to reprocessing and use. Mallinckrodt has not developed any performance tests that may be used to determine if the performance of the single use tracheal tube stylet has been altered by reprocessing and subsequent use.

5. Can visual inspection determine if performance has been affected?

No. Visual inspection cannot determine whether the thin film of lubricant coating on the lumen of the polymer sheath remains.

Thus, application of FDA's risk of inadequate performance flowchart demonstrates that Mallinckrodt's tracheal tube stylets present a **high risk** of inadequate performance after reprocessing. Accordingly, the device itself should be categorized as **high risk** under FDA's RPS.

IV. Conclusion

For the reasons discussed above, Mallinckrodt requests that FDA change the risk classification for urethral catheters in Appendix 2 from "moderate" to "high." Mallinckrodt also requests that tracheostomy inner cannulas and tracheal tube stylets be added to the "Respiratory" section of Appendix 2, both with risk categorizations of "high."

Mallinckrodt appreciates the opportunity to comment on the application of the RPS to its single use devices.

Sincerely,

Roger A. Keller

Roger A. Keller
Vice President, Secretary
and General Counsel

Nosocomial infections continue to complicate the clinical course of critically ill patients and, consequently, to create substantial economic and human costs. In 1985, the Centers for Disease Control reported that 5.7% of all hospitalized patients acquired nosocomial infections, which were defined as infections not present or incubating before hospital admission. At that time, annual spending for the treatment of nosocomial infections was approximately $1 billion.[1] Six years later, although the prevalence of nosocomial infections remained stable (about 6% of hospitalized patients), the estimated costs of treatment had escalated to between $5 billion and $10 billion.[2] More than 80,000 deaths each year have been directly linked to the development of nosocomial infections.[3] Subsequent reports are expected to report similar trends.

Although nurses are aware of infection control measures, inconsistent application of these measures continues to occur.[4-6] Inadequate infection control is of particular concern because one third of nosocomial infections are preventable.[1] In this article, we present up-to-date information on the risk of acquiring nosocomial infections, highlight the most common sites of these infections, and discuss strategies for preventing and controlling nosocomial infections in the ICU. The goals are to improve awareness and understanding of risks for infection and encourage consistent application of infection control measures by all ICU nurses to promote more favorable outcomes for patients.

PREVALENCE OF NOSOCOMIAL INFECTIONS

The prevalence of nosocomial infections in hospitalized patients is approximately 6%,[1] and a disproportionate 20% of these occur in critically ill patients,[6] even though ICUs account for only 5% of all hospital beds.[7] The prevalence of nosocomial infections is 5 to 10 times greater in ICU patients than in patients on general units, and use of mechanical ventilation, urinary catheters, and intravascular devices (all routine in the ICU) are major factors contributing to this disparity.[8]

Kennedy[9] describes the ICU as an "epidemiological jungle" because of the abundance of organisms that proliferate in these units. The predominant organisms responsible for nosocomial infections include *Pseudomonas aeruginosa* (13%), *Staphylococcus aureus* (12%), coagulase-negative staphylococci (10%), *Candida* (10%), enterococci (9%), and enterobacter (8%).[10]

CONTRIBUTING FACTORS

Factors common to ICU patients that contribute to the risk of nosocomial infections include acuity of illness, response to physiological and psychological stressors, age and associated comorbidity, indiscriminate use of antibiotics promoting the development of antibiotic-resistant organisms, drug therapies for stress ulcer, sleep deprivation, protein-energy malnutrition, and understaffing. With the exception of understaffing, each of these factors increases patients' risks of nosocomial infections by altering the patients' immune response or changing the response to infection.

Acuity of Illness

During acute illness, energy is diverted from normal body functions to meet increased metabolic needs. As the severity of an illness increases, energy stores needed to sustain normal body processes such as immune function become depleted, reducing the ability of the patient to resist colonization by exogenous organisms (originating outside the body). Critically ill patients are also more susceptible to overgrowth of resistant endogenous microbes (originating inside the body) such as staphylococci on skin and mucosal surfaces and enterococci in the gastrointestinal tract.[11]

Physiological and Psychological Stressors

Physiological stressors resulting from injury and illness and psychological stressors such as noise, pain, anxiety, and isolation are a few of the many stressors encountered daily by ICU patients.

The stress response is the same whether the stressor is physical or psychological. The initial "fight or flight" response to a stressor includes neuroendocrine suppression of the function of lymphoid tissue. The goal at this stage is to redirect energy for use in the fight-or-flight response.[12] Adrenocorticotropic hormone is released by the pituitary gland and stimulates the adrenal cortex to secrete cortisol. Cortisol, the primary hormone responsible for depressed immune function, suppresses synthesis of antibodies; reduces the number of lymphocytes and macrophages; and promotes stabilization of lysosomal membranes, inhibiting the release of hydrolases needed to destroy organisms.[13] These changes culminate in the decreased ability of leukocytes to attack microorganisms.

During the second stage of the stress response, the resistance phase, energy continues to be diverted to sustain the response until the host can reverse the process or until exhaustion of resources occurs and death ensues. The stage of exhaustion is often marked by overwhelming infections resulting in vascular collapse from a shock state.[13]

The stress response can also produce local changes that alter natural barriers to infection. For example, stress enhances secretion of salivary proteases, which decay fibronectin, a substance responsible for coating oral mucosal cells. The breakdown of fibronectin promotes adherence of gram-negative organisms to and colonization of structures in the upper part of the airway.[14]

Age and Comorbidity

Approximately 48% of all patients admitted to the ICU are more than 65 years old.[15] Elderly patients are less resistant to infection than their younger counterparts are.[16] Calianno[17] reported that mortality from bacterial nosocomial pneumonia is five times more likely in patients more than 65 years old. One possible explanation for this increased susceptibility is the progressive atrophy of the thymus that occurs with age; the atrophy causes a decrease in cell-mediated immunity, as shown by depressed production of T lymphocytes.[18] Also, natural defenses in the elderly are compromised. Respiratory ciliary action, respiratory excursion, and the cough reflex decrease, placing older patients at risk for nosocomial respiratory infections.[19]

The higher prevalence of chronic illnesses among the elderly also contributes to the risk for nosocomial infections.[16] The types of infections that may develop are linked to the specific alterations in the host defense produced by the chronic illness (eg, chronic lung disease, chronic renal failure, diabetes).[20] For example, elderly patients with chronic lung disease have a higher prevalence of bacterial nosocomial pneumonia caused by *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Branhamella catarrhalis* than do younger patients.[21]

Indiscriminate Use of Antibiotics and the Development of Resistant Organisms

Current practices for prescribing antibiotics are influenced by clinicians' preferences, marketing pressure from pharmaceutical companies, minimal adverse or toxic side effects with newer and more potent antibiotics, lack of precise methods for early identification of causative organisms, and concern over malpractice related to the potentially serious consequences of overwhelming infection in critically ill patients.[22] Broad-spectrum antibiotics are often prescribed for critically ill patients when signs and symptoms consistent with infection are present, white blood cell counts are elevated, or invasive procedures are required. Broad-spectrum antibiotics are often given when narrow-spectrum or organism-specific agents would be sufficient to resolve the infection.

Indiscriminate use of antibiotics leads to the elimination of a greater number of normal flora, thus enabling modified and more virulent organisms to produce infection.[22] These modified organisms have new characteristics against which standard agents are no longer effective. Traditionally, enterococcal infections were treatable with vancomycin. However, the development of multidrug-resistant enterococci that are resistant to vancomycin has resulted in bacteria that are now poorly controlled, despite the use of multiple, more potent antibiotics. The National Nosocomial

Infection Surveillance System reported that the percentage of nosocomial infections caused by vancomycin-resistant enterococci increased from 0.4% to 13.6% between 1989 and 1993.[23] Ultimately, patients infected with antibiotic-resistant pathogens have protracted hospitalizations, increased healthcare costs, and higher mortality rates.[22] Additionally, lapses in infection control with these patients increase the transmission of resistant organisms from one patient to another.[11] Thus, the discriminate use of organism-specific antibiotics is crucial to limiting the development of antibiotic-resistant organisms.

Prophylaxis for Stress Ulcers

Routine administration of antacids and histamine antagonists for prevention of stress ulcers in critically ill patients may increase the risk of infection.[24] The increase in gastric pH produced by these agents may attenuate the bactericidal effect of an acidic pH, thus promoting gastric colonization not only by gram-negative and gram-positive bacteria but also by yeasts. Retrograde esophageal colonization by these organisms then increases the risk of aspiration of microbes and subsequent nosocomial pneumonia.[24]

In a meta-analysis,[25] sucralfate was found to be associated with both a lower prevalence of pneumonia and a lower mortality rate than were other antacids and H_2-receptor antagonists. Sucralfate has been recommended because it does not alter gastric pH but works by forming a mechanical barrier at the site of ulceration.[26] Therefore, not only the primary effect of preventing stress ulcers but also the secondary effect of limiting bacterial growth, by maintaining a lower gastric pH, should be considered when prescribing prophylaxis for stress ulcers.

Sleep Deprivation

Krueger and Madge[27] reported alterations in sleep patterns during infectious diseases. Lack of the usual quantity and quality of sleep, including loss of normal progression through sleep cycles, adds to the stress critically ill patients experience and may alter immune function.[28] Interleukin-1, a protein known for its ability to amplify the immune response, has recently been linked with sleep regulation. During sleep deprivation, secretion of interleukin-1 is reduced, thus potentially limiting the cellular immune response.[29,30] The reduction in other factors associated with immune function (eg, interleukin-2, natural killer cells, and lymphokine-activated cells) known to occur during sleep deprivation may similarly contribute to the decline in resistance to infection.[31] However, further research is needed to describe the effects of sleep deprivation on immune function.

Malnutrition

Critically ill patients often experience hypermetabolic states as a consequence of physiological and psychological stressors, and these states lead to various degrees of malnutrition.[32,33] Catabolism of protein, carbohydrate, and fat stores and changes in the use of micronutrients (vitamins and minerals) deplete energy sources and may compromise host defensive mechanisms by reducing the production of immune cells.[34,35] Protein malnutrition has been linked with a breakdown of the intestinal mucosal lining that allows bacteria to move through the disrupted barrier into the lymph and bloodstream to produce infection.[35] A second mechanism for bacterial movement from the bowel, bacterial translocation, the process of bacterial movement through an intact mucosal barrier, has also been linked to protein malnutrition.[36]

Understaffing

Recent data from an investigation by the Centers for Disease Control and Prevention indicate that understaffing may be a risk factor for nosocomial infections.[37,38] When the patient-to-nurse ratio increases, the provision of routine nursing measures such as turning the patient, suctioning, and complying with aseptic technique may decline. To determine risk factors associated with an increase in bloodstream infections associated with use of central venous catheters during a protracted outbreak of the infections, Fridkin et al[38] analyzed multiple variables, including use of total parenteral nutrition, days of mechanical ventilation, and severity of illness. During the outbreak, patients' characteristics were unchanged, but patient-to-nurse ratios increased significantly. When data were analyzed by using a logistic regression model, the

occurrence of catheter-associated bloodstream infections was associated with a higher patient-to-nurse ratio. The investigators concluded that reductions in the number of nursing staff to less than a critical number during the outbreak may have contributed to the increase in the infections, because time constraints made adequate catheter care less likely.[36]

SITES OF INFECTION

The three major sites for nosocomial infections in the ICU are the respiratory system (31%), the urinary tract (24%), and the bloodstream (16%). Common diagnoses for infections at these sites are pneumonia, urinary tract infection, and septicemia.[39]

Respiratory System

The prevalence of hospital-acquired pneumonia, defined as a nosocomial pneumonia that occurs more than 48 hours after hospital admission but is not incubating at the time of admission, is not known, because this type of pneumonia is not a reportable illness.[40] Current estimates suggest a prevalence of 5 to 10 cases per 1000 admissions, with a 6- to 20-fold increase for patients receiving mechanical ventilation.[40] Hospital-acquired pneumonia is the second most common nosocomial infection but has the highest mortality (approximately 30%) and morbidity and prolongs the mean duration of hospitalization by an average of 7 to 9 days per patient.[40,41] Endogenous and exogenous factors place critically ill patients at risk for nosocomial pneumonia (Table 1).

Tracheal intubation is the most significant risk factor for the development of hospital-acquired pneumonia.[39,42] An endotracheal tube compromises the natural barrier between the oropharynx and the trachea and impairs natural defenses such as coughing and mucociliary action. If healthcare personnel or respiratory equipment harbor pathogenic flora, these organisms can be directly inoculated into the tracheobronchial tree.[40] The endotracheal tube can also become coated with a bacterial biofilm that may embolize into the airway.[43] Instillation of normal saline, a common practice during suctioning, may also facilitate direct entry of bacteria into the respiratory tract. In an in vitro study, Hagler and Traver[44] found that passing a suction catheter through an endotracheal tube dislodged up to 60,000 viable colonies of bacteria. When 5 mL of normal saline was instilled, as many as 310,000 colonies of bacteria were dislodged. In addition, as previously described, flora from the lower part of the intestine may colonize the stomach, be aspirated into the trachea, and contribute to the development of nosocomial infections.[40,45]

In addition, contaminated subglottic secretions, pooled above an inflated endotracheal cuff, may leak into the lower part of the respiratory tract. Two studies[46,47] suggest that removal of pooled secretions by continuous aspiration may decrease the risk of hospital-acquired pneumonia.

Table 1 Risk factors for nosocomial pneumonia

Endogenous
Age greater than 70 years
Alcoholism
Cardiopulmonary disease
Depressed level of consciousness
Diabetes
Malnutrition
Severe underlying disease
Exogenous
Abdominal or thoracic surgery
Conditions favoring aspiration
Endotracheal intubation
Nasogastric intubation
Supine positioning
Immobility
Prolonged mechanical ventilation
Use of antibiotics
Use of H_2 blockers or antacids
Use of immunosuppressive agents

Vallés et al[46] compared continuous aspiration of subglottic secretions to routine care in a group of patients intubated for more than 3 days. The prevalence of ventilator-associated pneumonia for the experimental group was half that for the control group. In a related study,[47] researchers concluded that aspiration of subglottic secretions around the cuff of the endotracheal tube was the most important risk factor for the development of pneumonia during the first 8 days of intubation.

Additional factors associated with the risk of hospital-acquired pneumonia include the duration of mechanical ventilation, presence of chronic lung disease, use of a nasogastric tube, and bronchoscopy.[14] Finally, poor nutritional status and immunosuppression

increase the risk for pneumonia.

Although use of broad-spectrum antibiotics has improved the prognosis for patients with hospital-acquired pneumonia, prevention continues to be the most important strategy. Critical care nurses can incorporate a number of strategies into routine practice to minimize the risk of hospital-acquired pneumonia (Table 2).

Table 2 Strategies for preventing nosocomial pneumonia

General
- Educate staff members about characteristics and transmission modes of pathogens common to the unit or institution.
- Routinely assess patients for changes in lung sounds, sputum color or production, and redness or drainage around stoma sites.
- Eliminate obtaining samples from patients and respiratory equipment for routine culturing of microorganisms.
- Wash hands before and after providing mouth care and before and after coming in contact with respiratory equipment and tracheal tubes.
- Use sterile water rather than tap water for mouth care of immunosuppressed patients or if waterborne organisms have been identified.
- Vaccinate patients at high risk for pneumococcal pneumonia.

Suctioning
- Provide a clean manual resuscitation bag for each patient.
- Suction oropharyngeal secretions as needed to avoid accumulation of oral secretions.
- Use sterile technique when using open-suctioning techniques.
- Use sterile solutions to clear secretions from in-line suctioning devices.
- Before deflating the cuff of the tracheal tube, suction secretions above the cuff by passing the catheter orotracheally, then provide a positive-pressure breath during deflation.
- Monitor tracheal cuff pressure with a manometer, minimal seal, or minimal leak technique every 8 hours to ensure an adequate seal and avoid overpressurization.
- Provide routine, meticulous mouth care.

Mechanical ventilation
- Change ventilator circuits no more frequently than every 48 hours.
- Drain accumulated condensate in ventilator tubing into a fluid trap or other collection device, particularly before repositioning the patient.
- Avoid backflow of condensate into tracheal tubes or humidification devices.

Nasogastric tubes and enteral feedings
- Assess patency and placement of nasogastric tubes routinely.
- Elevate the head of the bed 30° or more to prevent gastric reflux of organisms into the lung.
- Institute feeding as soon as possible to prevent breakdown of gut mucosa and possible bacterial translocation to the lung.
- Assess patients for signs of feeding intolerance: no bowel sounds, abdominal distension, increased residual volume, emesis.
- Discontinue use of nasogastric tubes as soon as clinically feasible.

Urinary Tract

The genitourinary tract is the most common site of nosocomial infection in the acute care setting, accounting for 40% of all hospital-acquired infections. Catheterization and instrumentation of the urinary tract are implicated as precipitating factors in approximately 80% of the cases.[48] Groups at high risk for urinary tract infection include patients who are female, elderly, diabetic, immunocompromised, critically ill, incontinent, malnourished, or who require extended hospitalization.[49]

Although there is no consensus on the precise distinctions between the terms bacteremia, sepsis, and septic shock, general agreement exists on the order in which these states occur. If bacterial infections in the urinary tract are not adequately treated, bacteria may enter the bloodstream, a condition called bacteremia. The point at which a systemic inflammatory response to this infection occurs is termed sepsis.[50] Unchecked sepsis causes a state known as septic shock, characterized by profound hypotension and marked abnormalities in perfusion. Although most bacteremias are clinically insignificant, as many as 4% progress to septicemia, with mortality rates as high as 50%.[48]

With normal bladder function, urine flushes through the urethra, removing bacteria adhering to the urethral walls. The presence of an indwelling catheter hinders the cleansing action of this protective mechanism.[51] The longer the catheter remains in the bladder,

the greater is the risk of infection; the infection rate doubles from 50% at 2 weeks to 100% if the catheter remains in place for more than 4 weeks.[5]

Mechanisms involved in the development of nosocomial urinary tract infections include contamination with the patient's fecal flora and cross-contamination by hospital personnel. As a result, bacteria gain entry to the urinary tract via both the lumen and the external surface of the catheter.[49]

Critical care nurses are in an optimal position to prevent unnecessary catheterization and to monitor the length of time a catheter is in place. Several measures can be used to minimize the potential for nosocomial urinary tract infections (Table 3).

Table 3 Strategies to prevent nosocomial urinary tract infection

- Use alternatives to indwelling catheters whenever possible (eg, external catheters, incontinence pads, bladder control techniques).
- Anticipate patients' catheterization needs. For example, if excess sediment or clots are present in the urine, insert a three-way catheter to facilitate sterile irrigation.
- Select smaller gauge urinary drainage catheters for insertion.
- Use sterile technique to insert urinary drainage catheters.
- Maintain a closed catheter system.
- Use universal precautions when emptying urine or obtaining specimens.
- Avoid cross-contamination by using an individual container for each patient when emptying catheter drainage bags.
- Change drainage bags that are leaking, contain excess sediment, or are malodorous.
- Secure urinary drainage catheters to the patient's thigh.
- Keep tubing and drainage bag below the level of the bladder at all times to prevent backflow of urine.
- Prevent stasis of urine by assessing tubing for kinks and obstruction.
- For male patients, cleanse the external meatus with soap and water and thoroughly dry the area twice a day and as needed.
- For male patients, avoid use of powders because of potential irritation of the meatus.
- Routinely assess patients for fecal incontinence, provide thorough cleansing, and use fecal incontinence bags as indicated.
- Monitor intake and output to ensure adequate fluid balance.

Bloodstream

Intravascular devices provide access to the vascular system for administration of fluids and drugs and for hemodynamic monitoring. These devices bypass skin defenses, thus becoming direct portals of entry for microorganisms into the bloodstream. In the ICU, bloodstream infections occur at a rate two to seven times greater than the rate among the medical-surgical population and, in one study,[7] accounted for double the length of stay in the unit. The average attributable mortality, defined as mortality directly related to the infection, apart from mortality that may be due to underlying conditions, is 26%.[7]

Infections associated with use of central venous catheters are most often due to colonization of the insertion site by bacteria normally present on the skin (*Staphylococcus epidermidis*).[52] Contamination of the lumen from frequent disconnection to administer medications or obtain blood samples is a second predisposing factor contributing to central venous catheter infections.[9,53] Interestingly, the risk of infection associated with use of triple-lumen catheters is as much as three times greater than the risk associated with use of single-lumen catheters.[54] Nonetheless, the most critical factor associated with the development of a catheter-related infection is the length of time the catheter remains in place.[55] More than 40% of bloodstream infections in ICUs are associated with short-term use of central venous catheters.[6] Although central venous catheters are considered short term, they are often left in place longer than necessary. Thus, consideration of the need for a catheter in each patient is essential for limiting infections associated with use of intravascular devices.

The rates of bloodstream infections associated with use of central venous and peripheral catheters vary.[55] Jarvis et al[10] reported rates of 2.1% to 30.2% per 1000 catheter days for central venous catheters and rates of 0% to 2% for peripheral catheters. Skin characteristics of the insertion site may account for differences in the prevalence of bloodstream infections between the two types of catheters, because temperature and moisture of the skin affect the

rate of colonization.[55] Skin in central locations is oilier and moister than skin in peripheral areas, thus enhancing conditions for bacterial colonization.[56] Another factor is the proximity of central sites to sources of contamination: oral, nasal, and tracheal secretions for catheters in the neck or subclavian area; and feces and urine for femoral catheters.[55] Patients with unexplained fever and signs and symptoms of localized infection most likely have a catheter-related infection. Their catheters should be removed and samples obtained for microbial culture.[53]

Two broad strategies to limit infections associated with use of intravascular devices are standardization of the procedures for care of the insertion site[57] and improvement in catheter design[58] and material.[59] In a descriptive observational study of 116 episodes of site care, Roach et al[57] found significant differences between two hospitals and within hospital units in the following practices: frequency of site care, use of ointment and skin adhesive, type of dressing, and duration of care. They concluded that well-defined site care protocols, familiar to all staff, and monitoring of care on a regular basis were needed to limit bloodstream infections. Furthermore, periodic evaluation is necessary to assess the need for central devices according to the patient's unique risks. Several measures can be used to minimize the prevalence of catheter-related infections (Table 4).

Modifications in catheter design may assist in decreasing infection risk. Segura et al[58] clinically tested a new hub design that significantly reduced catheter-related sepsis when compared with a control (4% vs 16%, respectively). In addition, catheters are being designed with the intention of preventing ascending infections by bonding antibiotics to the internal and external surfaces of the devices. Antimicrobial cuffs placed under the patient's skin at the insertion site are likewise being used to limit ascending infections.[60]

Studies on the efficacy of antibiotic-bonded catheters have produced mixed results. Both Greco and Harvey[61] and Kamal et al[62] reported a reduced prevalence in the rate of catheter infections when antibiotic-bonded catheters were used. In a randomized clinical trial of catheters bonded with silver sulfadiazine and chlorhexidine, Ciresi et al[63] found no difference in the rates of catheter-induced infections or sepsis when catheters with or without bonding were used. One explanation for these mixed findings may be the use of different combinations of pharmacological agents for the treatment of gram-positive bacteria, gram-negative bacteria, and fungal organisms.

MINIMIZING RISK

The increased acuity of illness in ICU patients, the frequent use of invasive devices and procedures, and the frequent contact with staff members provide multiple opportunities for exposure to and transmission of pathogens.[64] Successful prevention of nosocomial infections requires attention to their sources and to practices that promote their development.

Table 4 Management of IV catheters to prevent nosocomial infection

- Standardize insertion technique and care for all peripheral, central venous, and arterial catheters.
- Select catheters with as few lumens as necessary for the patient's needs.
- Avoid use of femoral catheters in patients with fecal or urinary incontinence.
- Use aseptic technique to insert catheters.
- Ensure that others inserting catheters use aseptic technique.
- Stabilize cannula and tubing, and maintain a sterile occlusive dressing at the site of insertion.
- Label insertion sites and all tubing with date and time of insertion.
- Inspect insertion sites every 8 hours for signs of infection, and record the findings.
- Replace nonocclusive dressings as specified by hospital policy (usually every 72 hours).
- Replace peripheral catheters per hospital policy (usually every 48-72 hours), when indications for use are no longer present, fever of unknown origin develops, or catheters have been inserted under less than optimal circumstances such as IVs placed emergently outside the hospital or during cardiac arrest.
- Change dressings per hospital policy. Cleanse the insertion site with povidone-iodine in a circular motion from inside to outside.
- Avoid guidewire replacement of central venous catheters; use a different insertion site when possible.

Knowledge of situations that compromise infection control and promote contamination is a meaningful start, but recognition must be followed by actions directed toward changing the behavior of nurses and other healthcare professionals. It is not only appropriate but also ethically correct for a nurse to speak out when aseptic technique is not followed. Because critical care nurses are the primary advocates for each patient's well-being, it is their responsibility to ensure that each patient receives uncompromised care.[65] The following are some basic, but important, examples that highlight appropriate infection control practices.

Hand Washing

Most preventable nosocomial infections are related to inappropriate infection control practices. Ignac Semmelweis recognized this fact in 1847.[66] At that time, the Vienna General Hospital had two obstetrical divisions, both delivering approximately 3500 babies each year. Obstetricians and medical students performed deliveries in division 1, and nurse midwives and their students delivered babies in division 2. Approximately 600 to 800 maternal deaths due to puerperal fever occurred annually on division 1 compared with 60 deaths per year on division 2. Seeking the reason for this discrepancy, Semmelweis discovered that physicians and medical students performed autopsies on a daily basis, whereas the midwives and the midwives' students did not. He hypothesized that the fevers were caused by an unknown substance on the cadavers that was transmitted to the new mothers. A hand-washing policy was instituted that entailed using "a chlorine solution until the skin was slippery and the cadaver smell was gone."[66] The following year, the death rate due to childbed fever did not differ between the two divisions. Several years later, Florence Nightingale requested scrub brushes and imposed sanitary regulations in field hospitals after observing that more soldiers died of fevers and infections than of battle wounds.[67] These simple yet elegant illustrations exemplify the relationship between the simple act of hand washing and the prevention of nosocomial infections in the past and serve as reminders of its importance in the present.

Today, consistent and meticulous hand washing (Table 5) remains the most important contributing factor related to reduction of the frequency of nosocomial infections in the ICU.[6] Because pathogens can survive on the hands for 30 minutes to several hours, hand washing significantly decreases the number of pathogens on the skin and contributes to decreases in patients' morbidity and mortality.[6,68] Additionally, hand washing minimizes the chance that healthcare workers will themselves acquire infections.[6,68]

Unfortunately, numerous studies have shown lack of adherence to the simple, inexpensive, and effective process of hand washing before and between contacts with patients in the ICU. In these studies, hand washing was carried out only 21% to 42% of the time.[4,6] The most common reasons cited by healthcare providers for not complying were being too busy, having a limited exposure to infectious patients, and wishing to avoid skin irritation from cleansing agents.[6] Although circumstances continue to improve (eg, sinks are closer to the patients, cleansing agents cause less irritation, and infection control education has become more accessible), noncompliance persists.[4,6]

Nails, Jewelry, and Lotion

Most microorganisms on the hands are under and around the nails. Short natural nails are preferable to artificial nails to minimize the number of bacteria and fungi around the nail and to prevent glove puncture. Clear nail polish is preferable for visual inspection during cleaning under the nails. However, optimally, healthcare professionals should avoid using

Table 5 Proper hand-washing technique

1. Wet hands under running water.
2. Dispense a minimum of 3-5 mL of soap or detergent, and thoroughly distribute it over all areas of both hands.
3. Vigorously wash all surfaces of hands and fingers for at least 10-15 seconds, including backs of hands and fingers and under the nails.
4. Rinse to remove soap, and thoroughly dry hands.
5. Use a paper towel to turn the faucet off.

any nail polish or artificial nails. Nail polish chips easily and can cause problems with infection.

Rings and other jewelry may increase the likelihood of tearing gloves and harboring microorganisms. Lotion may help decrease dermatitis and dryness related to hand washing and frequent use of gloves. Lotion can decrease the dispersal of bacteria on the hands. Small bottles are best, however, because with use, large containers can become contaminated.[69]

Gloves and Gowns

Gloves and gowns have been recognized as effective barriers against the transmission of microbes but are not 100% effective in protecting the wearer or patients. Universal precautions promote complacency, and gloves furnish yet another excuse not to wash the hands.[70] Gloves are not a shield that makes hand washing unnecessary. Hand washing should be performed before and after each contact with patients regardless of what barriers are used. Gloves are not meant to be reused for the same patient or among different patients. Therefore, hands should not be washed while the gloves are on. While wearing gloves, healthcare providers should avoid actions that predispose patients to contamination, including emptying urine drainage bags before performing hands-on care. Gowns are indicated only when clothing may become soiled.[68]

INSTITUTIONAL STRATEGIES

The current focus on patients' outcomes is an excellent means of increasing awareness of problems related to nosocomial infections. Prevention of these infections is a win-win situation, simultaneously improving care and reducing costs. This concept can be included in critical pathways for high-risk groups and incorporated into continuous-quality-improvement designs to ensure that prevention of nosocomial infections maintains a prominent position. These strategies will increase the focus on infection control practices and on evaluation of the usefulness of the practices and, it is hoped, result in improved compliance.

Rather than direct attention to infrequent clusters of infection that represent only 2% to 3% of all nosocomial infections, nurses should focus their efforts on areas of highest risk, specific to the ICU population in the particular setting.[71] Using a data-based approach, rather than guidelines, gives greater credence to recommendations. For example, having each ICU monitor the numbers and types of nosocomial infections and having the pharmacy monitor adherence to guidelines for use of antibiotics provides staff with valuable information related to everyday practices.[72,73]

The Joint Commission on Accreditation of Healthcare Organizations states that a hospital-wide approach, including a standing infection control committee, must be taken to coordinate infection control practices.[74] A multidisciplinary approach is essential to guide and support these efforts, and nurses are critical to the success of this endeavor. Clinical specialists, case managers, and nurse practitioners are in excellent positions to detect areas for improvement and to influence practice. Even more important are bedside nurses, the most direct consumers of infection control recommendations.[71]

Successful infection control requires that each member of the healthcare team recognize that humans are the primary source of nosocomial infections. Successful control also mandates awareness that, both individually and collectively, all healthcare practitioners are pivotal to the prevention of nosocomial infections.[69] Compliance can be increased by including nurses in decision making and in formulating directives.[75] Nursing staff can play an integral role in relaying information to surveillance professionals, and, in turn, infection control professionals can directly interact with staff to share information. Encouraging nurses to participate in research activities related to infection control may also enhance willingness to accept and use infection control practices less casually.

Education is inherently linked to a comprehensive infection control strategy; it ties together individuals and groups of personnel directly and indirectly involved in infection control. Nurses' lack of sufficient knowledge of microbiology and inconsistent application of infection control measures continue to be issues.[76] However, another inservice program is not the answer. Both knowledge and motivation are critical for effective infection control, and motivation

to change behavior is not learned in an occasional class. Sustained unit-based education must be the vehicle for presenting data that convince staff that problems exist and persuade staff members to use optimal infection control practices.[71]

Feedback about infection control practices is another influential strategy to successfully reduce the number of nosocomial infections. Data on the number and type of infections in specific populations of patients and reports on infection control practices in the unit should be expressed in a manner that staff can understand. Establishing benchmarks for these data to improve compliance with infection control is an additional method of influencing practice.

Using performance feedback (providing information about past performance with educational instruction to promote improvement) provides an opportunity to correct behavior and move toward established benchmarks.[77] This strategy can be made more personal, timely, and effective by direct observation of nurses and physicians. In one study,[78] memos were used to alert staff members that their hand-washing technique was ineffective. This mechanism increased compliance to 98% in the experimental group compared with 26% in a control group not receiving feedback.[78] A similar observational study[79] found 97% compliance with performance feedback versus 37% with educational classes alone. Therefore, an integrated approach is essential to generate and maintain change.

CONCLUSION

Nosocomial infections in the ICU pose a significant problem today and will continue to do so. The ICU population will continue to grow older, and acuity will consistently escalate. As patients have comorbid conditions and receive more invasive care, practitioners will struggle with fewer antibiotics to offer as treatment for infection. Therefore, critical care nurses must become increasingly vigilant in attempts to use essential prophylactic techniques to minimize nosocomial pneumonia, nosocomial urinary tract infections, and catheter-related infections. Basic though the strategies included in Tables 2 to 5 may be, they cannot be effective if ICU personnel do not heed them. Not all nosocomial infections can be prevented, but it is prudent for healthcare professionals to recognize, implement, and use appropriate comprehensive strategies to prevent these infections and optimize patients' outcomes. As Florence Nightingale observed, "The first responsibility to the patient is to do no harm."[67] ✚

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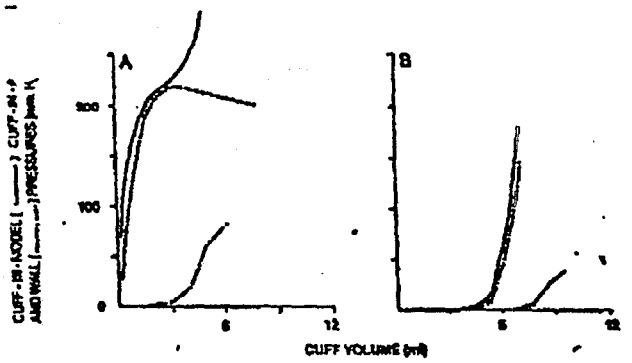

Figure 1. Pressure-volume relationships for low residual volume cuff (A) and high residual volume cuff (B). Cuff in air relationship (....), cuff in model relationship (————), and wall pressure (–·–·–). Reproduced from Black AMS and Seegobin RD, Anaesthesia 1981;36:498–511, with permission.

function of cuff radii of curvature (r_1, r_2), cuff thickness (t), and cuff principal circumferential mechanical stresses (σ_1, σ_2). In view of the time and temperature dependence of cuff material, it is difficult to determine a more exact relationship, even experimentally (personal communication, Portex Ltd., Hythe, Kent, U.K.). The relationship of the form

$$Pic = Ptw + Pic \text{ (in air)},$$

as suggested by Horni et al. (5), has not been substantiated 3).

Brodsky et al. demonstrates a relationship between cuff volume and intracuff pressure, but the concept of bronchial wall pressure and its variable relationship to cuff volume and intracuff pressure is omitted, which may be misleading to readers.

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In Response:

Dr. Magee's letter makes an interesting and useful point: the pressure transmitted to the bronchial wall is less than the pressure inside the cuff by an amount related to the pressure needed to maintain the inflation of the cuff itself. As mentioned, this factor is difficult to calculate or to measure experimentally, although the formula given, which considers the inflation factor to be equal to the pressure of the cuff when inflated while surrounded by air, may at least give a rough estimate of the actual wall pressure. The inflation factor is likely to be much higher for a "high pressure/low volume" cuff than for the "low pressure/high volume" cuff. Within each class of cuffs this factor is likely to be similar, although different cuff materials and geometries may cause some variation. Thus comparison of different "low pressure/high volume" cuffs is appropriate.

We agree with Dr. Magee that the wall pressure is the relevant variable, but we emphasize that when double-lumen tubes are properly used it is the wall pressure at *occlusion of the bronchus* that counts. Our study demonstrated that occlusion occurred at small *volumes* and *pressures* when some of the low pressure/*"high volume"* cuffs were used. The actual wall stress imparted by these cuffs is unknown, but in any case it can only be less than or equal to the cuff pressure itself. A further issue relates to the match between tube size and bronchus size because a mismatch will result in occlusion at an atypical volume and pressure. The effects of such a mismatch have not been investigated.

Finally, we point out that the actual contribution of bronchial cuff pressure/volume relationships to morbidity can only be made by studying animal models in which the integrity of the bronchial mucosa and wall can be assessed.

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Reuse of a Disposable Stylet With Life-Threatening Complications

Key Words: EQUIPMENT, DISPOSABLE—reuse.

To the Editor:

Karis recently suggested the advantages of reusing disposable single-use devices (1). Although I am a family practitioner, the letter came to my attention because of its relevance to the startling course of one of my patients. This 72-yr-old woman entered initially for elective foot surgery only to develop life-threatening complications from a reused disposable device.

My patient underwent bilateral foot surgery in early 1990. A difficult endotracheal intubation was performed after initial inadvertent esophageal intubation. On entering the esophagus, a 10-cm section of a Mallinckrodt Satin-Slip 14F aluminum stylet with plastic sheath broke off in the esophagus. This was not detected at the time.

Postoperatively her course was initially uneventful, but

after a few days she began to have vague gastrointestinal symptoms and developed a low-grade fever. Although she had an extensive diagnostic workup over the next few weeks, no definitive diagnosis was made. Eventually, however, she presented with an acute abdomen. Emergency laparotomy revealed peritonitis with the 10-cm fragment of the broken stylet perforating the duodenum.

The following should be noted in this case:

(a) The stylet used here was aluminum (Mallinckrodt and Portex manufacture aluminum stylets), which is a brittle metal to begin with and more likely to break with reuse. The manufacturer cautions against reuse, citing the breakage hazard on the package.

(b) Upon examination several bends indicating reuse were observable in the 10-cm fragment of the broken stylet.

In view of this experience, Dr. Karis' position on reuse of disposable single-use devices appears too cavalier. Although one is tempted to hold that manufacturers promote one-time use from a strictly economic standpoint, safety factors and the high cost of product liability insurance sustained by the manufacturers must be considered.

Transmission of infection and chemical irritation from traces of sterilizing solutions and gases are known risks of reusing single-use devices. In addition, malfunction (for example, most intubating stylets lose their malleability with reuse) and weakening with the tendency for failure and breakage need to be considered when one-time use equipment is reused.

One cannot estimate what reuse and resterilization of single-use devices can do to their integrity because of the impossibility of standardizing and enforcing reuse criteria. Certainly the patient should not be exposed to the risks of reuse of single-use devices especially when reuse involves a very small fraction of overall health costs. We can ill afford to be penny wise and pound foolish, in the best interests of patient care, when it comes to the issue of disposables.

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The Burden of Progress: A Fable

Key Words: COMPLICATIONS, ANESTHETIC, MORTALITY AND MORBIDITY

To the Editor:

Dr. Arthur Keats' article on anesthetic mortality (1) deserves serious consideration. I cannot fault his logic, nor can I argue his points with scientific counterpoints. Yet I am troubled by what he has to say. Had our forefathers in 1846 embraced his gloomy outlook, they might have concluded that the introduction of anesthesia should be halted because not only did it render surgical care more expensive, it also spawned new mechanisms of maiming and killing surgical patients. I am sure that Dr. Keats would not want us to draw such conclusions. I accept his message as an attempt to provoke us to examine every dogma that comes our way. But we have to be careful not to exchange the dogmas he decries for the alternate dogma that no innovation can be accepted without scientific proof of its value. To make that point, I offer the following fable.

The Burden of Progress

> Now comes the pain of truth, to whom 'tis pain;
> O folly! for to bear all naked truths,
> And to envisage circumstance, all calm,
> That is the top of sovereignty.
>
> —John Keats

I was reading an article on the burden of progress as I flew to Atlanta, where I was to change planes to fly to Chicago. It never came to that.

Despite a layer of dense clouds at the Atlanta airport, the plane made a smooth, precise landing. As I disembarked, the captain stood at the door of the cockpit to greet the passengers. I stopped and asked, "How could you find the airport in such soup? Surely not by looking at a road map!" He smiled and waved me into the cockpit to show me his instruments.

My heart sank. Having just read about the burden of progress, I asked: "Do these instruments ever mislead you? What are the sensitivity and specificity of the instruments? Do they ever fail? There are so many of them (it was a DC 9-31), won't they confuse and distract you?"

He sighed and said, "Nothing is perfect. Yes, there are examples where pilots have been distracted by irrelevant data or wrong reports. But that is rare. And we do have back-ups. Here, for example, is our magnetic compass. It needs electricity only for illumination and works even during power failure." "I am glad, " I said, "that you still have such an old, proven, reliable, time-honored instrument as a back-up. Do you use it often? And if so, why bother with all those fickle electronic things in the first place?" "Well, I'll tell you," he said, "I haven't flown by that magnetic compass in years. We are required to have one on board, but we don't use it. For example, here in Atlanta Stone Mountain has a magnetic core that worries our old-fashioned compass!"

By then the last passenger had left the plane. The captain said he was going off duty and, before flying as a passenger to Chicago, had time to chat. So did I. We sat in a lounge and he told me how advance after technical advance over the years had transformed the cockpit of commercial and even private aircraft. He said, "Every instrument is designed to fill a gap left by the limitations of human physiology or performance."

"In anesthesia it is similar, " I said, "but it seems that every advance has brought us new complications. We may eliminate the dilemma of unrecognized esophageal intubation, only to replace it with the predicament of having a